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ART UNIT	PAPER NUMBER
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NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/501,984	SCHAUB, ADREAS F.	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-16 and 18-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-16,18-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/9/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 12-16 and 18-27 are pending in this application. Addition of new claims 24-27 is acknowledged. Claims 1-11 and 17 stand canceled.

2. Claims 12-16 and 18-27 are examined.

Claim Rejections - 35 USC § 112

3. The rejection of claim 15 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendment to claim 15.

4. The rejection of claim 18 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendment to claim 18.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 12, 13, 15, 16, and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Leuven (US Patent 4,267,168) in view of Bringloe (US Patent 4,765,478).

The claimed invention is drawn to a method for reducing the frictional force between an item to be delivered and the birth canal of the mother in human vaginal child birthing, which comprises introducing a composition comprising a physiologically

acceptable organic lubricant and no alkali metal salts of metaphosphates, wherein the composition is in the form of a paste, gel, cream, suppository, or foam, in an effective amount into the birth canal of the woman (see claim 12).

Van Leuven teaches a composition which is useful as a lubricant to be used during delivery at the time of birth, and does not contain alkali metal salts of metaphosphates (abstract). The composition comprises glycerine, which provides a very soothing action on tender tissue, and therefore acts as an organic lubricant (col. 6, lines 1-2). The composition may be applied to vaginal tissue of the baby's mother (col. 6, lines 52-54). Since vaginal tissue is part of the birth canal, the composition is applied to the birth canal. The composition may also comprise inert stable thickeners, such as hydroxymethylated cellulose, in order to control viscosity (col. 6, lines 62-65).

Van Leuven does not specifically teach that the composition is in the form of a gel.

Bringloe teaches that hydroxymethyl cellulose is a known gelling agent in topical compositions (see col. 3, lines 46-53).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to formulate the compositions taught by Van Leuven in the form of a gel; thus arriving at the claimed invention. Hydroxymethyl cellulose is a known gelling agent, as taught by Bringloe, and thus one skilled in the art would reasonably expect that the use of hydroxymethyl cellulose in a composition would result in the composition being in the form of a gel. One skilled in the art would have been motivated to add hydroxymethyl cellulose to the composition in order to control

viscosity, as taught by Van Leuven, since a thicker (i.e., more viscous) composition would result in the lubricant composition adhering better to the wall of the birth canal, thus providing a greater lubricant effect. One would reasonably expect success from the use of hydroxymethyl cellulose as a gelling agent (as taught by Bringloe) in the composition taught by Van Leuven because Van Leuven teaches that hydroxymethyl cellulose may be added to the composition in order to control viscosity.

Regarding claim 13, Van Leuven teach that glycerine provides skin conditioning and a very soothing action (col. 5, line 58 - col. 6, line 2), and therefore an organic substance (i.e., glycerine) brings about a lubricant effect in the composition, or confers a lubricant effect through formulation of the composition.

Regarding claim 15, Van Leuven teaches that the polymer hydroxymethyl cellulose may be added to the composition (col. 6, lines 62-65).

Regarding claim 16, Van Leuven teaches that the composition comprises hydroxymethyl cellulose, a known gelling agent, and therefore would form a gel.

Regarding claim 18, Van Leuven teaches that the composition may comprise the gelling agent (col. 6, lines 62-65), and therefore would result in a hydrogel.

Regarding claim 19, Van Leuven teaches that the lubricant glycerine is present from 4 to 10% (col. 5, lines 58-59 and claim 1).

Regarding claims 20-22, Van Leuven teaches that the composition comprises the biocidal agents sodium polypectate and silver ion in amounts of 100-400 ppm and 13-250 ppm, respectively (for example, see claim 1), or 0.01-0.04% and 0.0013-0.025%, respectively. These amount ranges overlap those of the claimed invention, and one

skilled in the art would be motivated to manipulate the amounts of said biocidal agents from within said ranges by routine experimentation, in order to optimize the biocidal activity of the composition.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Leuven (US Patent 4,267,168) in view of Bringloe (US Patent 4,765,478) as applied to claims 12, 13, 16, and 18-22 above, and further in view of Hardy (US Patent 4,981,686).

Claim 14 of the claimed invention is drawn to the method as claimed in claim 13, wherein the organic substance with a lubricant effect comprises a natural or synthetic oil, fat or wax.

The invention of the combined references is delineated above (see paragraph 5).

The invention of the combined references does not specifically teach the presence of an organic lubricant which is a natural or synthetic oil, fat or wax.

Hardy teaches a vaginal lubricant which soothes vaginal tissue (col. 1, lines 55-65). The composition comprises a preferable combination of lubricants selected from petrolatum, coconut oil, lanolin, mineral oil, and stearyl alcohol (col. 2, lines 32-36). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add a natural or synthetic oil, fat or wax to the composition taught by the invention of the combined references; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because the addition of lubricant(s) such as petrolatum, coconut oil, lanolin, mineral oil, and/or

stearyl alcohol provides the benefits of desired lubricity without being irritating, as taught by Hardy (col. 2, lines 32-36). Additionally, it is prima facie obvious to combine two compositions, each of which is taught by the prior art, to be useful for the same purpose (in this case, as lubricants), in order to form a third composition to be used for the very same purpose. See MPEP 2144.06 One would reasonably expect success from the addition of lubricants as taught by Hardy to the composition taught by the invention of the combined references because both references are drawn to lubricant compositions which are applied to vaginal tissue.

Response to Arguments

8. Applicant's arguments filed 1/6/09 have been fully considered but they are not persuasive.

Applicants argue that Bringloe does not relate to human vaginal childbirth or to a method for reducing the frictional force between an item to be delivered and the birth canal of the mother, and thus a person skilled in the art would not be motivated to combine these two references relating to completely different subject matter.

This argument is not persuasive because the teachings of Bringloe are relied upon merely to demonstrate the nature of hydroxymethyl cellulose, i.e., that it is a gelling agent. Thus, one skilled in the art would recognize that when hydroxymethyl cellulose is employed as a thickener as taught by VanLeuven, a gel would result.

Applicants also argue that, although it has long been known to use cellulose derivatives as thickeners, this recitation in Bringloe does not cure the deficiencies of

Van Leuven. Applicants argue that it is clear from the disclosure on lines 9-16, col. 6 of Van Leuven that pH is maintained between 7.2 and 7.8 and it is very important to maintain this pH to avoid gelling of polypectate. Applicants conclude that Van Leuven teaches that gelling is undesirable and Van Leuven seeks to maintain the liquid characteristic of the composition.

This argument is not persuasive because the passage to which Applicants refer is talking about the phase separation of a single component of the composition, and not the composition as a whole. Therefore, this teaching of VanLeuven does not provide any conclusory evidence that gelling is undesirable for the composition as a whole, but only that it is desired to keep polypectate from phase separating.

Applicants also argue that Van Leuven discloses that the addition of inert thickeners (e.g. hydroxymethyl cellulose) will "not alter the basic characteristics of the liquid biocidal composition" (cf. col. 6, lines 62-68 of Van Leuven).

This argument is not persuasive because VanLeuven clearly teach that compositions of appropriate viscosity are preferred (for example, see col. 5, lines 1-3), including those of higher viscosity (col. 5, line 24). Furthermore, the form of the final composition (liquid vs. gel) would be a result-effective variable, depending on the components and amounts used, and it would be within the purview of the skilled artisan to manipulate the form of the composition by optimizing the amounts of the components already taught in VanLeuven, including hydroxymethyl cellulose, especially in light of the fact that a thicker composition would result in the lubricant composition adhering more to the wall of the birth canal, thus providing a greater lubricant effect. Finally, the

named thickeners would not alter the basic characteristics of the liquid biocidal composition, which are to afford good lubrication and biocidal activity. Therefore, absent a teaching of the unexpectedness of forming the composition as a gel, forming the composition as a gel would be obvious.

Regarding claim 14, Applicants argue that Bringloe does not cure the deficiencies of Van Leuven and no combination of Van Leuven and Bringloe, or Van Leuven, Bringloe, and Hardy renders obvious the features of independent claim 12. Applicants argue that the combination of Van Leuven, Bringloe, and Hardy does not render obvious all of the features of claim 14 which depends from claim 12.

This argument is not persuasive because Applicants have not made any arguments apart from those already made above; accordingly, the rejection is maintained for reasons stated above.

9. Claims 12, 13, 15, 16, 18-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara et al (US Patent 3,971,848) in view of Bringloe (US Patent 4,765,478).

The claimed invention is drawn to a method for reducing the frictional force between an item to be delivered and the birth canal of the mother in human vaginal child birthing, which comprises introducing a composition comprising a physiologically acceptable organic lubricant and no alkali metal salts of metaphosphates, wherein the composition is in the form of a paste, gel, cream, suppository, or foam, in an effective amount into the birth canal of the woman (see claim 12).

Kasahara et al teach a composition having lubricating property comprising fucoidin and alginic acid (abstract) and does not contain alkali metal metaphosphates. The composition may be used to lubricate the birth canal in human bodies to facilitate the delivery of the fetus (col. 5, lines 16-32). The composition may be optionally mixed with carboxymethyl cellulose (col. 5, lines 39-42).

Kasahara et al do not specifically teach that the composition is in the form of a gel.

Bringloe teaches that carboxymethyl cellulose is a known gelling agent in topical compositions (see col. 3, lines 46-53).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to formulate the compositions taught by Kasahara et al in the form of a gel; thus arriving at the claimed invention. Carboxymethyl cellulose is a known gelling agent, as taught by Bringloe, and thus one skilled in the art would reasonably expect that the use of carboxymethyl cellulose in a composition would result in the composition being in the form of a gel, especially in light of the fact that the lubricant is "mucous and thready" (col. 2, lines 7-8), which would favor a gel composition. One skilled in the art would have been motivated to add carboxymethyl cellulose to the composition in order to optimize the viscosity, as taught by Kasahara et al, since a thicker (i.e., more viscous) composition would result in the lubricant composition adhering more to the wall of the birth canal, thus providing a greater lubricant effect. One would reasonably expect success from the use of carboxymethyl cellulose as a gelling agent (as taught by Bringloe) in the composition taught by

Kasahara et al because Kasahara et al teach that carboxymethyl cellulose may be added to the composition.

Regarding claim 13, Kasahara et al teach that the composition comprising fucoidin and alginic acid has a lubricating property, and therefore an organic substance (i.e., fucoidin/alginic acid) brings about a lubricant effect in the composition, or confers a lubricant effect through formulation of the composition.

Regarding claim 15, Kasahara et al teach that the fucoidin lubricant is a polymer (col. 2, lines 54-59).

Regarding claim 16, Kasahara et al teach that the composition may comprise carboxymethyl cellulose, a known gelling agent, and therefore would form a gel.

Regarding claim 18, Kasahara et al teach that the gelling agent carboxymethyl cellulose may be added to the composition (col. 5, lines 39-42), and therefore would result in a hydrogel.

Regarding claim 19, Kasahara et al teach that the lubricant of fucoidin/alginic acid is present in amounts of 72.2-85.1% (see Examples).

Regarding claims 20 and 22, Kasahara et al teach that the composition may include an antiseptic (col. 5, lines 48-49), which would prevent infection.

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara (US Patent 3,971,848) in view of Bringloe (US Patent 4,765,478) as applied to claims 12, 13, 15, 16, 18-20, and 22 above, and further in view of Hardy (US Patent 4,981,686).

Claim 14 of the claimed invention is drawn to the method as claimed in claim 13, wherein the organic substance with a lubricant effect comprises a natural or synthetic oil, fat or wax.

The invention of the combined references is delineated above (see paragraph 7).

The invention of the combined references does not specifically teach the presence of an organic lubricant which is a natural or synthetic oil, fat or wax.

Hardy teaches a vaginal lubricant which soothes vaginal tissue (col. 1, lines 55-65). The composition comprises a preferable combination of lubricants selected from petrolatum, coconut oil, lanolin, mineral oil, and stearyl alcohol (col. 2, lines 32-36).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add a natural or synthetic oil, fat or wax to the composition taught by the invention of the combined references; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because the addition of lubricant(s) such as petrolatum, coconut oil, lanolin, mineral oil, and/or stearyl alcohol provides the benefits of desired lubricity without being irritating, as taught by Hardy (col. 2, lines 32-36). Additionally, it is prima facie obvious to combine two compositions, each of which is taught by the prior art, to be useful for the same purpose (in this case, as lubricants), in order to form a third composition to be used for the very same purpose. See MPEP 2144.06 One would reasonably expect success from the addition of lubricants as taught by Hardy to the composition taught by the invention of the combined references because both references are drawn to lubricant compositions which are applied to vaginal tissue (which is a part of the birth canal).

11. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara (US Patent 3,971,848) in view of Bringloe (US Patent 4,765,478) as applied to claims 12, 13, 15, 16, 18-20, and 22 above, and further in view of Van Leuven (US Patent 4,267,168).

Claim 21 of the claimed invention is drawn to the method as claimed in claim 20, wherein the amount of active pharmaceutical ingredients is from 0.0001 to 10% by weight (see claim 21).

The invention of the combined references is delineated above (see paragraph 7). Kasahara et al teach that an antiseptic may be present in the composition (col. 5, lines 48-49).

The invention of the combined references is silent with respect to the amount of antiseptic.

Van Leuven teaches that, in compositions used as a lubricant during delivery at the time of birth, it is known to use the biocidal agents sodium polypectate and silver ion in amounts of 100-400 ppm and 13-250 ppm, respectively (for example, see claim 1), or 0.01-0.04% and 0.0013-0.025%, respectively.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use biocidal agents (i.e., antiseptics) in amounts taught by Van Leuven in the composition of the combined references; thus arriving at the claimed invention. One skilled in the art would have been motivated to use said amounts because Van Leuven fairly teaches and suggests useful amounts of biocidal agents in

lubricant compositions used during delivery at the time of birth. Furthermore, said amounts overlap those of the claimed invention, and one skilled in the art would be motivated to manipulate the amounts of said biocidal agents from within said ranges by routine experimentation, in order to optimize the antiseptic activity of the composition.

Response to Arguments

12. Applicant's arguments filed 1/6/09 have been fully considered but they are not persuasive.

Applicants argue that Bringloe does not relate to human vaginal childbirth or to a method for reducing the frictional force between an item to be delivered and the birth canal of the mother, and thus a person skilled in the art would not be motivated to combine these two references relating to completely different subject matter.

This argument is not persuasive because the teachings of Bringloe are relied upon merely to demonstrate the nature of carboxymethyl cellulose, i.e., that it is a gelling agent. Thus, one skilled in the art would recognize that when carboxymethyl cellulose is employed as taught by Kasahara, a gel would result

Applicants also argue that Kasahara discloses that the composition is an aqueous solution, and does not change its consistency even when adding further compounds such as carboxymethyl cellulose.

This argument is not persuasive because Kasahara's teaching that the compositions is an aqueous solution does not exclude the composition in the form of a gel, as many gels are formed of aqueous solutions with a thickener (such as

carboxymethyl cellulose). Instead, one skilled in the art would recognize that a "mucous, thready" composition, as taught by Kasahara (col. 2, lines 7-8), would favor formation as a gel. Additionally, Kasahara does not provide any explicit teaching that the consistency of the composition does not change upon the addition further compounds such as carboxymethyl cellulose; on the contrary, Kasahara describes the addition of carboxymethyl cellulose as improving lubrication because said viscous substance forms synergistically a liquid **film of much greater thickness** which is not likely to escape between the two frictional interfaces (emphasis added; see col. 2, lines 29-40); one skilled in the art would reasonably envisage a gel from said description. It is further pointed out that the form of the final composition (liquid vs. gel) would be a result-effective variable, depending on the components and amounts used, and it would be within the purview of the skilled artisan to manipulate the form of the composition by optimizing the amounts of the components already taught in Kasahara, including carboxymethyl cellulose, especially in light of the fact that a thicker composition would result in the lubricant composition adhering more to the wall of the birth canal, thus providing a greater lubricant effect.

Applicants also argue that, since Kasahara teaches that too high a solids content would result in too high a viscosity, and Kasahara only contains the solid product in an amount of 1% by weight, and that Kasahara teaches that the composition for human delivery be in the form of an aqueous solution even in the presence of thickeners such as carboxymethyl cellulose, Kasahara teaches away from the presently claimed method by teaching that a viscous composition is undesirable and counterproductive.

This argument is not persuasive. Never does Kasahara say that a viscous composition is "undesirable and counterproductive". On the contrary, Kasahara teaches that viscous substances improve lubrication (col. 2, lines 29-40), and only teaches that a solids content more than 15% leads to too high a viscosity, and does not make any conclusory statement against the composition being viscous or in the form of a gel. Applicant's reference to a solids content of 1% in Kasahara is only one example taught in Kasahara, and the invention of Kasahara is not limited to just this teaching. Furthermore, as stated above, Kasahara does not provide any explicit teaching that the consistency of the composition does not change upon the addition of further compounds such as carboxymethyl cellulose. Furthermore, Kasahara teaches that its compositions are in a mucilaginous form (col. 2, lines 66-68), which is consistent with Applicant's description of its own compositions (see page 5, 3rd full paragraph of Applicant's specification).

Regarding claim 14, Applicants argue that no combination of Kasahara and Bringloe, or Kasahara, Bringloe, and Hardy renders obvious the features of independent claim 12 based on the reasoning above. Applicants argue that the combination of Kasahara, Bringloe, and Hardy does not render obvious all of the features of claim 14 which depends from claim 12.

This argument is not persuasive because Applicants have not made any arguments apart from those already made above; accordingly, the rejection is maintained for reasons stated above.

Regarding claim 21, Applicants argue that no combination of Kasahara and Bringloe, or Kasahara, Bringloe, and Van Leuven renders obvious the features of independent claim 12 based on the reasoning above. Applicants argue that the combination of Kasahara, Bringloe, and Van Leuven does not render obvious all of the features of claim 21 which depends from claim 12.

This argument is not persuasive because Applicants have not made any arguments apart from those already made above; accordingly, the rejection is maintained for reasons stated above.

13. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara (US Patent 3,971,848) in view of Bringloe (US Patent 4,765,478) as applied to claims 12, 13, 15, 16, 18-20, and 22 above, and further in view of JP 46-24256 (English abstract submitted herewith).

Claim 23 of the claimed invention is drawn a method for reducing the frictional force between an item to be delivered and the birth canal of the mother in human vaginal child birthing, which comprises introducing a composition comprising a physiologically acceptable polyacrylic acid lubricant and no alkali metal salts of metaphosphates, wherein the composition is in the form of a paste, gel, cream, suppository, or foam, in an effective amount into the birth canal of the woman (see claim 23).

The invention of the combined references is delineated above (see paragraph 7). Kasahara et al teach that the composition may also comprise sodium polyacrylate (col. 5, lines 40-41).

Kasahara et al do not teach that the sodium polyacrylate is present as a lubricant.

JP '256 teaches that sodium polyacrylate is useful as a lubricant during birth (see abstract).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use sodium polyacrylate as a lubricant in the composition of the combined references; thus arriving at the claimed invention. One skilled in the art would be motivated to do so because JP '256 fairly teaches and suggests that sodium polyacrylate is useful as a lubricant during birth, and therefore one skilled in the art would reasonably expect the sodium polyacrylate in the composition of Kasahara et al to function as a lubricant. Furthermore, while JP '256 teaches that the lubricant is useful in veterinary applications, Kasahara et al teach that lubricants useful in veterinary applications would be equally effective in human bodies as well (see col. 5, lines 16-32). One would reasonably expect success from the use of sodium polyacrylate in the composition of the combined references because Kasahara et al teach that sodium polyacrylate may be present in the composition, and JP'256 teaches that sodium polyacrylate is useful as a lubricant.

Response to Arguments

14. Applicant's arguments filed 1/6/09 have been fully considered but they are not persuasive.

Applicants argue that, due to the significant differences between human and animal delivery, a person skilled in the art would not have been motivated to employ a veterinary lubricant, i.e. the one disclosed in JP '256, for human vaginal childbirth as taught by Kasahara. Applicants argue that this is also taught by the declarations signed by Prof. Saling and Prof. Litschigi submitted in response to the previous Office Action. Applicants argue that no combination of the cited art would have rendered obvious a method according to the claimed invention.

This argument is not persuasive because Kasahara teach that their method of lubrication is useful for lubricating the birth canal at the time of parturition in animals, and also states that attainment of similar effects in human bodies can also be fully expected (col. 5, lines 16-20). Therefore, one skilled in the art would, in fact, be motivated to consider the use of veterinary parturition lubricants, and reasonably expect said lubricants to attain similar effects in humans, especially given the fact that the JP '256 reference states that its lubricant has no harmful effects. Additionally, the declarations to which Applicants refer make no mention of the cited prior art, or of any comparison between human and veterinary parturition.

It is further pointed out that Kasahara et al also teach that the composition may comprise sodium polyacrylate (see col. 5, lines 40-41), and the addition of said

compound is preferable for affording lubrication for attaining a good lubrication at the time of parturition (see col. 2, lines 17-26).

New Grounds of Rejection

15. Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara (US Patent 3,971,848) in view of Bringloe (US Patent 4,765,478) and JP 46-24256 (English abstract) as applied to claim 23 above, and further in view of Van Leuven (US 4,267,168) and further evidenced by Spruce et al (WO 01/74359) and Gold (US Patent 5,342,617).

Claim 24 of the claimed invention is drawn to the method of claim 23, wherein the composition further comprises a cellulose, a humectant, and at least one isotonicizing substance.

The invention of the combined references is delineated above (see paragraphs 9 and 13). Kasahara et al further teach that the composition may comprise a cellulose such as carboxymethyl cellulose (col. 5, line 40) and may also comprise glucose in order to heighten the solubility of the composition (col. 5, lines 43-45). Glucose is a known isotonicizing substance; as evidence, Spruce et al teach that isotonicizing agents include glucose (see page 28, lines 10-11).

The invention of the combined references does not teach the presence of a humectant in the composition.

VanLeuven teaches that the humectants propylene glycol and glycerine (i.e., glycerol) are used in compositions which act as lubricants to be used during delivery at the time of birth (abstract).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add propylene glycol and/or glycerine to the composition of Kasahara; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because the addition of said humectant(s) provides the benefits of a very soothing action on tender tissue, as with glycerin, and some bacteriocidal activity, as with propylene glycol, as taught by Van Leuven (see col. 6, lines 1-2 and col. 5, lines 47-49, respectively). One would reasonably expect success from the addition of propylene glycol and/or glycerin as taught by VanLeuven to the composition of Kasahara because both references are drawn to compositions useful for lubricating the birth canal during delivery.

Regarding claim 25, Kasahara teach that carboxymethyl cellulose may be added to the composition (col. 5, lines 39-42).

Regarding claim 26, VanLeuven teaches the use of propylene glycol and glycerin in lubricants used during delivery at the time of birth, as described above.

Regarding claim 27, Van Leuven teaches the use of propylene glycol in lubricants used during delivery at the time of birth, as described above. While the invention of the combined references does not specifically teach the presence of hydroxyethyl cellulose, one skilled in the art would reasonably expect said cellulose to function in an equivalent manner to carboxymethyl cellulose, since both are known

cellulose derivatives used as gelling agents in human tissue lubricants, as evidenced by Gold (see col. 1, lines 21-28), and Applicants have not presented any evidence demonstrating any unexpectedness of the use of hydroxyethyl cellulose over other cellulose derivatives.

Conclusion

No claims are allowed at this time.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is

(571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Lakshmi S Channavajjala/

Primary Examiner, Art Unit 1611

March 25, 2009